IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF TENNESSEE NASHVILLE DIVISION

RUTH SMITH, Individually and as Widow for the Use and Benefit of Herself and the Next of Kin of RICHARD SMITH, Deceased,	)	**Case #: 3:05-00444**
	)	**Judge Trauger**
Plaintiff,	)	
-against-	)	
PFIZER INC., PARKE-DAVIS, a division of Warner-Lambert Company and Warner-Lambert Company LLC, WARNER-LAMBERT COMPANY, WARNER-LAMBERT COMPANY LLC and JOHN DOE(S) 1-10,	)	
Defendants.	)	

MEMORANDUM IN SUPPORT OF PLAINTIFF'S MOTION *IN LIMINE* TO PRECLUDE ANY TESTIMONY OR DISCUSSION BY DEFENDANTS THAT THEY COULD NOT HAVE AMENDED THE NEURONTIN LABEL OR ISSUED STRENGTHENED WARNINGS WITHOUT PRIOR FDA APPROVAL

Plaintiff Ruth Smith, as the Widow for the use and benefit of herself and the next of kin of Richard Smith, deceased, by and through her undersigned counsel, respectfully requests an order precluding Defendants Pfizer Inc. and Warner-Lambert Company LLC from arguing that they could not have amended the Neurontin label without prior approval of the United States Food and Drug Administration. As demonstrated below, not only would such testimony or discussion be false, but it should be precluded under Fed. R. Evid. 402 and 403 because their probative value are outweighed by the risk of undue prejudice, confusion of issues, misleading the jury, undue delay, and waste of time.

ARGUMENT

Plaintiff anticipates that Defendants will offer testimony and argue at trial that they could not have amended the Neurontin label to include warnings of increased risks for suicidality, the need for monitoring due to adverse mood and behavior changes, and other warnings advocated by Plaintiff, without prior approval of the FDA. Such claims are false and misleading. Though subject to FDA oversight, Defendants were responsible for ensuring that adequate warnings appeared on the label of Neurontin.

POINT I

CLAIMS THAT DEFENDANTS COULD NOT HAVE AMENDED THE NEURONTIN LABEL WITH FDA APPROVAL WOULD BE FALSE

Any suggestion that only the FDA could have changed the label for Neurontin is false and raises a misleading and confusing question as to whether Defendants or the FDA was ultimately responsible for the failure to warn patients and physicians of the drug's true risks. The Food, Drug and Cosmetic Act (the "Act") *expressly* requires a drug manufacturer to immediately inform the public of newly discovered dangers rather than waiting for the FDA to act. *See McEwen v. Ortho Pharm. Corp.*, 270 Ore. 375, 528 P.2d 522, 534-35 (1974) (copy attached hereto as Exhibit A); *see also* 44 Fed. Reg. 37,447 (1979). The intention of the Act is "to protect consumers from dangerous products." *United States v. Sullivan*, 332 U.S. 689, 696 (1948); *see FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000). 21 C.F.R. § 201.57 states that "labeling shall be revised to include a warning *as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved*." (Emphasis added.) As the U.S. Supreme Court recently stated in *Wyeth v. Levine*, FDA regulations provide that a drug manufacturer may make changes in labeling under certain circumstances and need not obtain approval from the FDA prior to making the changes:

> There is, however, an FDA regulation that permits a manufacturer to make certain changes to its label before receiving the agency's approval. Among other things, this "changes being effected" (CBE) regulation provides that if a manufacturer is changing a label to "add or strengthen a contraindication, warning, precaution, or adverse reaction" or to "add or strengthen an instruction about dosage and administration that is intended to in crease the safe use of the drug product," it may make the labeling change upon filing its supplemental application with the FDA; it need not wait for FDA approval. §§ 314.70(c)(6)(iii)(A), (C).

555 U.S. ___, 129 S. Ct. 1187, 1196, 173 L. Ed. 2d 51 (2009).

Moreover, the Supreme Court made it crystal clear that it is the legal obligation of a manufacturer to promptly take steps to strengthen its warnings to consumers of newly discovered dangers and risks of an approved product:

> Yet through many amendments to the FDCA and to FDA regulations, it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times. It is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market. *See, e.g.*, 21 CFR §201.80(e) (requiring a manufacturer to revise its label "to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug"); § 314.80(b) (placing responsibility for post marketing surveillance on the manufacturer); 73 Fed. Reg. 49605 ("Manufacturers continue to have a responsibility under Federal law . . . to maintain their labeling and update the labeling with new safety information").

129 S. Ct. at 1197-98.

Furthermore, the Supreme Court also emphasized, in relation to any insinuation by Defendants that if they had changed the Neurontin label without FDA approval they could have been subject to charges of "misbranding," to the contrary that:

> The FDCA does not provide that a drug is misbranded simply because the manufacturer has altered an FDA-approved label; instead, the misbranding provision focuses on the substance of the label and, among other things, proscribes labels that fail to include "adequate warnings." 21 U. S. C. § 352(f).

129 S. Ct. at 1197.

Consequently, Defendants were permitted to strengthen their instructions and warnings for their Neurontin labels *at any time* without advance approval by the FDA. *See* 44 Fed. Reg. 37,447 (June 26, 1979) (emphasis added); *see also* 30 Fed. Reg. 993 (Jan. 30, 1965) (allowing a drug manufacturer to strengthen its warnings "in the interest of drug safety" at any time without FDA pre-approval to enable adoption of new warnings as soon as possible). Any argument or testimony that Defendants were required to obtain prior approval from the FDA before amending the Neurontin label to include warnings or information concerning an increased risk for suicide, etc., is simply false.

Further, although Defendants may argue that § 314.70 provides only temporary authority to strengthen a label, the FDA has discretion to keep a manufacturer's strengthened warning. 21 C.F.R. § 314.70. Assuming *arguendo* that Defendants had strengthened their Neurontin warning to include the risks and dangers alleged by Plaintiff, the FDA could have taken one of three possible courses of action. First, the FDA could have approved the warning in which case the label change would remain in effect. Second, the FDA could have taken no action and, again, the label change would remain in effect. *See* 56 Fed. Reg. 59,290 (Nov. 25, 1991). Third, the FDA could have disapproved of the strengthened warning and instructed the company to suspend distribution of the new label. 21 C.F.R. § 314.70(c)(7). Where the FDA disapproves of a strengthened label enacted by the manufacturer, however, that manufacturer is not exposed to retroactive penalties. *Id.* Indeed, federal regulations underscore the fact that Defendants had the ability to change their Neurontin warning, *sua sponte*, without fear of penalties by the FDA.

Also, the recently revised April 2009 label for Neurontin is in line with some of the warnings advocated by Plaintiff in this litigation. In the revised label, the **WARNINGS** section

begins with **Suicidal Behavior and Ideation**, and applies to "any indication" (not just on-label approved indications of epilepsy and post herpetic neuralgia):

> Antiepileptic drugs (AEDs), including Neurontin, increase the risk of suicidal thoughts or behavior in patients taking these drugs **for any indication.** Patients treated with any AED for any indication should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior.

See April 2009 Neurontin label, attached as Exhibit A (emphasis added).

Accordingly, the Court should preclude Defendants from arguing or offering testimony that they could not have strengthened the Neurontin label to include strengthened warnings or cautions that ingestion of Neurontin increases the risk for suicide, etc., without prior FDA approval. Such testimony or discussion would be contrary to well-settled federal regulations and case law and would likely cause confusion and prejudice by suggesting that the inadequacies of the Neurontin label were the responsibility of the FDA, rather than the manufacturer.

CONCLUSION

For the foregoing reasons, Plaintiff respectfully requests an order prohibiting Defendants from arguing or offering testimony that they could not have amended the Neurontin label to include warnings that ingestion of Neurontin increases the risk for suicidality without prior FDA approval.

Dated: April 16, 2010

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this the 16th day of April, 2010, I electronically filed the foregoing document with the Clerk of the Court, United States District Court for the Middle District of Tennessee, using the CM/ECF system. True and correct copies of the foregoing documents are being served via the Court's CM/ECF system on the following:

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